

# INFORMED CONSENT INFORMATION, CHECKLIST AND SAMPLE

## Macomb Community College, Institutional Review Board

### REQUIRED ELEMENTS OF INFORMED CONSENT

Researchers must obtain the ***informed consent*** of all study participants. For those less than 18 years of age, the researcher must obtain the informed consent of parents or legal guardian and each minor participant's ***assent***, which is defined as the minor participant's agreement to participate in the study.

The informed consent must provide the key information that that a reasonable person would want to have in order to make an informed decision about participating in the research. The most important information must be provided at the beginning of the form. It should include the following elements in order to facilitate participant understanding. **The elements should be included in sequential order and in clear, concise, focused language that participants will understand:**

1. Statement of the purpose of the research.\*
2. Short description of the methodology, including identification of any procedure that is experimental.\*
3. Expected duration of the subject's participation.
4. Description of foreseeable risks to participants, and benefits if any.
5. Disclosure of an alternative to the intervention that might be advantageous, if relevant.
6. Statement about the level of confidentiality of identifying information and plans to de-identify, including a statement as to whether or not identifiers will be removed from the data, and whether or not the data might be used for secondary research.
7. An offer to answer any questions the participant may have about the research and their rights as research participants, and an explanation of whom to contact, which must include the Principal Investigators and IRB Chair names titles, email addresses and/or phone numbers.
8. Statement that participation is voluntary, and that participants retain the right to withdraw from the study at any time without any negative consequences (for example, no loss of benefits to which the participant is otherwise entitled, or no impact on course grades).
9. Include a statement indicating that the participant is 18 years of age or older, unless parent or legal guardian has given consent and the minor has given assent.
10. Include a line for signature of participants, or if participant is a minor, a line for parent/legal guardian signature and a line for minor's signature indicating assent.

**\*For Research Involving Deception:** In situations where participants will be **deceived**, items 1 and 2 are omitted and participants are told (on the signed form) that disclosure of the purpose and/or methodology could bias the study outcomes. In this case, **after the study is complete**, each participant must be presented with a description of the purpose and methodology as carried out and this document must be signed by the participants "after the fact" to guarantee informed consent.

### SAMPLE Informed Consent Document

The following suggestions are offered as guidelines; the exact language is the decision of the researcher, but must be clear enough to ensure participant understanding. Keep in mind that the Institutional Review Board must determine if the participants are being giving **informed consent**. (Note: that in the case of participating minors, their parent/guardian gives consent and the minor gives **assent**.)

Dear participant:

I am conducting a study to determine (*concise research purpose*). In this study, you will be asked to (*state what the participant will be asked to do*). Participation should take no more than (*min. or hours*).

There are minimal risks to you, meaning no more risk than occurs on a normal, daily basis. **OR**

The risks to you include \_\_\_\_\_  
(*List possible psychological, physical, economic or other harm which could result from the study.*)

There are no expected benefits to participants other than (*list its educational value to participants, if any, or the potential knowledge gain that may be helpful to individuals in the future*).

All information will be handled in a strictly confidential manner, so that no one will be able to identify you when the results are recorded, reported or published. Identifiers will be removed from all participant data prior to analysis. No data will be stored for later, secondary research.

For any questions about the research, about your rights as a research participant, please feel free to contact (*name and title of principal researcher*) at (*phone/email*), or contact the Macomb IRB Chair (*name and title*) at (*phone/email*).

Your participation in this study is totally voluntary. You may withdraw at any time without negative consequences. If you wish to withdraw at any time during the study, simply contact the principal researcher or the IRB Chair listed above.

I understand the study described above and have been given a copy of the research description as outlined above.  I am 18 years of age or older and I agree to participate.

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

***If the participant is not of age (not 18 years old or older), address the above to the participant's parent or legal guardian, and include the following elements for signatures at the end of the consent form:***

I understand the study described above and have been given a copy of the description as outlined above. I agree to allow my son/daughter to participate with his/her assent.

\_\_\_\_\_  
Signature of Parent/Guardian

\_\_\_\_\_  
Date

***AND include the ASSENT language for minors:***

I understand what I must do in this study and I want to take part in the study.

\_\_\_\_\_  
Signature of Minor

\_\_\_\_\_  
Date

**Macomb Community College  
 Human Subjects Research  
 Consent Form Checklist of Required Elements**

YES	NO	N/A	Checklist of Consent Form Required Elements
			1. Is the consent form written in everyday ("lay") language?
			2. Is it free of any language that requires the subjects to waive their legal rights, including any release of the investigator, sponsor or college or its agents from liability for negligence?
			3. If minors are included in the study, are provisions made for obtaining parental/guardian consent and minor assent?
			4. Does the consent form include each of the following basic elements of informed consent?
			a. A clear statement that the study involved research, an explanation of the purpose(s) of the research, and the expected duration of the subject's participation.
			b. A brief, clear description of the procedures to be followed
			c. A description of any reasonably foreseeable risks or discomforts
			d. A description of any benefits to the subject or others
			e. A statement describing the extent to which confidentiality of records identifying the participant will be maintained.
			f. A statement regarding whether or not identifiers will be removed from the data, and whether or not the data might be used for secondary research.
			g. Information about whom to contact for answers to questions about the research study and the research subject's rights.
			h. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits, and the participant may discontinue participation at any time without penalty or loss of benefits.

If there was a "NO" response to any of the above questions, the consent form must be revised accordingly unless the investigator can satisfactorily justify why is it appropriate without revision.